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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,777	09/15/2003	Hassan Ahmad	2551-1-001	1508
23565	7590	04/01/2005	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			MCCORMICK EWOLDT, SUSAN BETH	
		ART UNIT		PAPER NUMBER
		1654		

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,777	AHMAD ET AL.	
	Examiner	Art Unit	
	Susan B. McCormick-Ewoldt	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 February 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 September 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and *Nigella sativa* as the species in the reply filed on February 24, 2005 is acknowledged. The traversal is on the ground(s) that Group I is a pharmaceutical composition drawn to treating hepatitis and immunological disorders and Group II is a method of treating the hepatic and immunological disorders using such composition, therefore, the searches would overlap. This is not found persuasive because the inventions are distinct and independent from each other; thus, separate searches would be required.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 24, 2005.

Claims Pending

Claims 11-25 are withdrawn from consideration. Claims 1-10 will be examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hepatitis, does not reasonably provide enablement for treating immunological disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: “Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is “undue,” not “experimentation.”” (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicted on the basis of quantity of experimentation required to make or use the invention. “Whether undue experimentation is needed is not a single, simple factual considerations.” (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case, are discussed below.

Inventions targeted for treating immunological disorders bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is high for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. It is noted that the instant claim encompasses immunological disorders that can be reduced, and yet the instant specification provides no working examples and no guidance that would permit the skilled artisan to use the invention.

In the instant case, Applicant has disclosed that the claimed composition is useful in treating immunological disorders. The claim specifically discloses treating immunological disorders in a human, while in the specification, Applicant provides no working examples and no guidance that would permit the skilled artisan to practice the invention commensurate with the *scope* of the instant claim. The claim also encompass using a composition to treat immunological disorders which is clearly beyond the scope of the instantly disclosed/claimed invention.

It is noted that there is not a single example in the instant specification, *working or prophetic*, which indicates that the product of the instant disclosure would treat immunological disorders. For example, the data found in the specification is inconclusive to support the breadth

of the claimed invention. Taking the examples of pages 42-46 into consideration, it appears that Applicant has found that claimed composition does have some effect on treating hepatitis. However, again, there is no indication that this response can be reasonably extrapolated to any immunological disorders treatment.

Again, the claim is drawn to specifically treating immunological disorders. However, Applicant has not demonstrated the effectiveness of the claimed composition on immunological disorders. The skilled artisan would not have a reasonable expectation that the response displayed in the instant specification would reasonably extrapolate to treatment of immunological disorders lacking substantial evidence in the specification as well as the prior art pertaining to the efficacy of the claimed composition.

The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the skilled artisan with specific treatment regimens that achieve a therapeutic benefit; however, the specification does not provide such guidance and fails to provide evidence that the claimed composition would treat immunological disorders. Without such guidance in the specification and the lack of correlative working examples, the claims would ***require an undue experimentation without a predictable degree of success on the part of the skilled artisan.***

In re Fisher, 427 F.2D 833, 166 USPQ 18 (CCPA 1970), held that “inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some ways on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; ***however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112;*** that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved.” (emphasis added).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A composition for treating hepatitis and immunological disorders comprising a therapeutically effective amount of *Nigella sativa* which is in a tablet, capsule, topical, suppository or intra-muscular form, is claimed.

Claims 1, 2, 4-6, 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Medenica (US 5,653,981).

Medenica (US 5,653,981) teaches using an extract of *Nigella sativa* for increasing the immune system function. Medenica also teaches how to administer the extract of *Nigella sativa* such as intramuscular, subcutaneous, intravenous, tablet, capsule or suppositories or the like. The teaching of Medenica meets the limitations of claims 1, 2, 4-10 as *Nigella sativa* and thus anticipates the claimed invention.

Claims 1, 2, 5, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shawkat (US 5,648,089).

Shawkat (US 5,648,089) teaches using *Nigella sativa* in an oral herb composition to treat patients diagnosed with active Hepatitis-B and Hepatitis-C (column 1, lines 20-35, 60 and claim 1). The teaching of Shawkat meets the limitations of claims 1, 2, 4 and thus anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medenica (US 5,653,981).

Medenica (US 5,653,981) teaches using an extract of *Nigella sativa* for increasing the immune system function. *Nigella sativa* has been found to help restore immune receptor cells in cancer patients. Medenica also teaches how to administer the extract of *Nigella sativa* such as intramuscular, subcutaneous, intravenous, tablet, capsule or suppositories or the like. Medenica does not teach the exact concentration of the claimed extract (column 3, lines 38-42; column 4, 13-15; column 5, lines 31-42).

The reference does not specifically teach the ingredients in the dosage forms claimed by Applicant. The dosage form of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the dosage form of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage form would have been obvious at the time of Applicant's invention.

The reference also does not specifically teach the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Claims 1, 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shawkat (US 5,648,089).

Shawkat (US 5,648,089) teaches using *Nigella sativa* in an oral herb composition to treat patients diagnosed with active Hepatitis-B and Hepatitis-C (column 1, lines 20-35, 60 and claim 1).

The reference does not specifically teach the ingredients in the dosage forms claimed by Applicant. The dosage form of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the dosage form of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage form would have been obvious at the time of Applicant's invention.

The reference also does not specifically teach the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary

No claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Lee
3-30-05
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PRIMARY EXAMINER